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IN THE UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. RIZO LOPEZ FOODS, INC., A CORPORATION, AND EDWIN RIZO AND TOMAS RIZO, Defendants.	CASE NO. _____ **COMPLAINT FOR PERMANENT INJUNCTION**

Plaintiff, the United States of America, by its undersigned counsel, on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, to enjoin and restrain Rizo Lopez Foods, Inc., a corporation, and Edwin Rizo and Tomas Rizo, individuals (collectively, "Defendants"), from violating: 21 U.S.C. § 331(a), by introducing or delivering for

introduction into interstate commerce, or causing to be introduced or delivered for introduction into interstate commerce, articles of food within the meaning of 21 U.S.C. § 321(f) that are adulterated within the meaning of 21 U.S.C. § 342(a)(4); and (b) 21 U.S.C. § 331(k), by causing articles of food within the meaning of 21 U.S.C. § 321(f) that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4).

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and all parties to this action under 21 U.S.C. § 332(a), 28 U.S.C. §§ 1331, 1337, and 1345.

3. Venue in this District is proper pursuant to 28 U.S.C. § 1391(b) and (c).

DEFENDANTS

4. Defendant Rizo Lopez, Inc. ("Rizo Lopez") is a California corporation. The company manufactures, receives, prepares, processes, packs, holds, and/or distributes refrigerated, ready-to-eat ("RTE") food, including, but not limited to, cheese, yogurt, and sour cream products. These products are manufactured at Rizo Lopez's facility located at 201 South McClure Road, Modesto, California 95357 (the "Facility"), within the jurisdiction of this Court.

5. Defendant Edwin Rizo is the Chief Executive Officer, co-owner, and President of Rizo Lopez. Along with Tomas Rizo, Edwin Rizo is the most responsible person at Rizo Lopez. Defendant Edwin Rizo oversees the company's overall operations, including manufacturing, receiving, preparing, processing, packing, holding, and distributing food, and shares responsibility in detecting, preventing, and correcting violative conditions at the Facility. He performs his duties at the Facility, within the jurisdiction of this Court.

6. Defendant Tomas Rizo is the Chief Financial Officer, co-owner, and Secretary of Rizo Lopez. Defendant Tomas Rizo is responsible for the company's distribution and promotion of Rizo Lopez products, and he shares responsibility with Edwin Rizo in detecting, preventing, and correcting violative conditions at the Facility. He performs his duties at the Facility, within the jurisdiction of this Court.

7. Defendants receive one or more components used to manufacture their RTE dairy

products from outside of California. For instance, Defendants received two shipments of rennet from Wisconsin, which they used to manufacture Cotija and Fresco cheese products.

8. Defendants manufacture and distribute dairy products throughout the United States sold under various brand names, including, but not limited to, Tio Francisco, Don Francisco, Rizo Bros, and 365 Whole Foods Market. Defendants also distribute dairy products in bulk as a contract manufacturer to multiple companies, including, but not limited to, Walmart, Inc., Sysco Corporation, and United Natural Foods, Inc., that independently distribute those dairy products throughout the United States.

FOOD SAFETY

9. *Listeria monocytogenes* ("*L. mono*") is a major pathogen, and one of several bacteria contained within the *Listeria* species ("*Listeria spp*."). *L. mono* can cause the disease listeriosis, a disease commonly contracted by consuming food contaminated with the bacterium. Listeriosis can be serious, even fatal, for vulnerable groups such as the elderly, newborns, and those with impaired immune systems. Complications from the disease can include pneumonia, central nervous system damage, endocarditis, localized abscesses, skin lesions, and conjunctivitis. Pregnant women may contract flu-like symptoms from listeriosis, and complications from the disease can result in miscarriages, stillbirth, and meningitis.

10. *L. mono* can survive and grow even when precautions are taken, such as maintaining food at refrigeration temperatures. *L. mono* can also colonize on moist surfaces such as floors, floor drains, wet areas, and processing equipment, and is often found in condensation or standing water, floors, food residues, processing equipment, and other niches in facilities.

11. The presence of *L. mono* in a facility where RTE dairy products are exposed to the processing environment allows for contamination of RTE dairy products and presents a serious danger to public health. To minimize the potential for *L. mono* contamination, it is necessary to have sanitation procedures that prevent contamination of food contact surfaces and eliminate niches where *L. mono* can become established, grow, and persist.

DEFENDANTS' VIOLATIONS

12. Defendants' food (*e.g.*, cheese, yogurt, and sour cream products) is food within the meaning of the Act, 21 U.S.C. § 321(f).

13. Defendants' food is adulterated within the meaning of 21 U.S.C. § 342(a)(4), in that it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or may have been rendered injurious to health. Such insanitary conditions include the presence of *L. mono* at Defendants' Facility.

14. To prevent insanitary conditions, food manufacturers must adhere to FDA's Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls ("CGMP") regulations (21 C.F.R. Part 117), which establish basic practices and conditions for food manufacturing operations. Food may be deemed adulterated within the meaning of 21 U.S.C. § 342(a)(4) if it is prepared, packed, or held in a facility that does not comply with these regulations. 21 C.F.R. § 117.1(a)(1).

15. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing to be introduced or delivered for introduction into interstate commerce, articles of food within the meaning of 21 U.S.C. § 321(f), that are adulterated within the meaning of 21 U.S.C. § 342(a)(4), in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. The insanitary conditions include, but are not limited to, the persistent presence of *L. mono* at Defendants' Facility and Defendants' failure to comply with the CGMP regulations.

16. Defendants violate the Act, 21 U.S.C. § 331(k) by causing articles of food, within the meaning of 21 U.S.C. § 321(f) that Defendants hold for sale after shipment of one or more of their components into interstate commerce, to become adulterated under 21 U.S.C. § 342(a)(4), in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. The insanitary conditions include, but are not limited to, the persistent presence of *L. mono* at Defendants' Facility and Defendants' failure to comply with the CGMP regulations.

17. FDA and other state and federal government agencies have found *L. mono* in Defendants' food and/or Facility in January and February 2024. FDA has determined that the same strain of *L. mono*

has likely persisted in Defendants' Facility since 2014. FDA has also determined, based on recent inspectional findings, that Defendants are operating their food manufacturing facility under insanitary conditions and failing to follow the food CGMP regulations in 21 C.F.R. Part 117.

L. mono Detected in Defendants' Food in January 2024

18. On or about January 3, 2024, the Hawaii State Department of Health collected a retail product sample of Defendants' Rizo Bros California Creamery brand Aged Cotija Mexican Grating Cheese (Defendants' "retail product sample"). On or about January 5, 2024, a Hawaii State Department of Health laboratory detected *L. mono* in the retail product sample.

19. Rizo Lopez recalled 344 cases of their Rizo Bros California Creamery brand Aged Cotija Mexican Grating Cheese on January 11, 2024.

CDC Listeriosis Investigation

20. On or about January 18, 2024, Center for Disease Control ("CDC") reopened its multistate, multi-year listeriosis investigation linked to Fresco, Cotija, and other similar cheeses. As part of this investigation, CDC first identified an individual sickened with listeriosis after consuming Defendants' Don Francisco Cotija cheese in 2014.

21. Since 2014, the CDC listeriosis investigation identified twenty-six individuals that had contracted listeriosis and collected twenty-six clinical *L. mono* isolates. Sixteen of these individuals reported consuming Fresco or other similar types of cheeses in the month prior to their illness, and three of them specifically reported consuming Defendants' Don Francisco brand Fresco or Cotija cheese products.

22. The CDC listeriosis investigation identified 26 cases from eleven states: Arizona (4), California (8), Colorado (4), Florida (1), Georgia (1), North Carolina (1), Nevada (1), Oregon (1), Tennessee (2), Texas (2), and Washington (1). Of these cases, four individuals were pregnant, including one who suffered a fetal loss, and twenty-three individuals were hospitalized because of listeriosis, including two individuals who subsequently died.

FDA's February 2024 Inspection of Defendants' Facility

23. FDA inspected Defendants' Facility between January 24 and February 23, 2024 (the "February 2024 inspection"). During this inspection, FDA collected two environmental subsamples that

tested positive for *L.* mono from Defendants' Facility: one from the inside of a tote that Defendants used to store exposed RTE Cotija cheese products, including the retail product sample that tested positive for *L. mono* on January 5, 2024; and the other from the bottom right corner of the Facility's cheese aging room door. Two *L. mono* isolates were derived from each of the *L. mono* positive subsamples.

24. During the February 2024 inspection, FDA investigators also observed insanitary conditions and documented violations including, but not limited to, Defendants':

a. Failure to clean and sanitize equipment in a manner that protects against contamination of food and food contact surfaces, as required by 21 C.F.R. § 117.35(a). For example, FDA investigators observed an employee spraying water onto the floor using a high-pressure nozzle adjacent to the machine used for vacuum packaging RTE cheese. The overspray of water aerosolized onto the conveyor belt—a food contact surface on which employees placed exposed RTE cheese wheels. Defendants' use of a high-pressure water hose in a food processing area can contribute to the spread of pathogens and can generate overspray, aerosols, and mist that can transfer pathogens, soil, debris, and filth onto previously cleaned surfaces;

b. Failure to provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning, as required by 21 C.F.R § 117.37(b)(4). For example, FDA investigators observed employees conducting flood-type cleaning while manufacturing exposed RTE cheese products. Pooled water accumulated throughout the Facility's cheese production room due to inadequate floor drainage. Pooled water is a suitable environment for *L. mono* and can lead to cross-contamination of food in the processing environment; and

c. Failure to ensure employees wash their hands after their hands may have become soiled or contaminated, as required by 21 C.F.R. § 117.10(b). For example, FDA investigators observed an employee picking up debris from the flooded wet floor of the cheese production room and proceeding to hand pack Cotija cheese without sanitizing their hands.

25. At the close of the February 2024 inspection, an FDA investigator issued a Form FDA-483 List of Inspectional Observations to Defendants Edwin Rizo and Tomas Rizo, listing the above-described CGMP violations and discussed the violations with them.

WGS Analysis

26. FDA used Whole Genome Sequencing ("WGS") to compare (a) the positive *L. mono* isolate identified in Defendants' retail product sample, (b) the twenty-six clinical *L. mono* isolates collected as part of the CDC listeriosis investigation, and (c) the four *L. mono* isolates derived from the two environmental subsamples collected during FDA's February 2024 inspection of Defendants' Facility.

27. WGS is performed on each bacterial isolate to determine the genomic sequence of its DNA, allowing for high resolution comparisons between isolates and a determination as to whether two isolates originated from the same source.

28. Using a public database maintained by the National Center for Biotechnology Information, the WGS data is compared against the WGS data of isolates that have been collected from previous food and clinical surveillance efforts to determine whether two or more isolates originated from the same source.

29. Based on its analysis of the WGS data, FDA identified a genetic match among (a) the positive *L. mono* isolate identified in Defendants' retail product sample, (b) the twenty-six clinical *L. mono* isolates collected as part of the CDC listeriosis investigation, and (c) the four *L. mono* isolates derived from the two environmental subsamples FDA collected from Defendants' Facility. This match indicates that this *L. mono* strain likely originated from the same source, Defendants' Facility.

30. When a pathogen isolate found in a food manufacturing facility matches a pathogen isolate from an ill patient, the match implies that the pathogen strain in the facility is capable of causing illness. Accordingly, because the isolates collected from Defendants' Facility matched the isolates from the CDC's listeriosis investigation, FDA has determined that the strain of *L. mono* in Defendants' Facility is capable of causing illness.

31. Because the isolate from the Defendants' retail product sample collected by Hawaii in 2024 and the clinical isolates collected by CDC since 2014 match the strain of *L. mono* found in Defendants' Facility during the February 2024 inspection, this strain of *L. mono* is likely a resident strain that has existed in Defendants' Facility since at least 2014. The presence of a resident strain in a

facility indicates previous sanitation efforts have been ineffective in eradicating the *L. mono* from the facility.

Defendants' Responses Are Inadequate

32. On or about February 2, 2024, FDA informed Defendants Rizo Lopez and Edwin Rizo that a strain of *L. mono* identified in an environmental subsample collected during the February 2024 inspection matched the strain of *L. mono* in the retail product sample and twenty-five[1] clinical isolates in the CDC listeriosis investigation. After further discussions among Defendants, FDA, and CDC, on or about February 5, 2024, Defendants recalled all RTE dairy products within expiry and temporarily ceased operations.

33. On February 12, 2024, FDA informed Defendants Rizo Lopez and Edwin Rizo that it detected the same strain of *L. mono* in the second environmental subsample that had been identified in the first environmental subsample, retail product sample, and twenty-five clinical isolates from the CDC listeriosis investigation.

34. On February 14, 2024, Rizo Lopez's Quality Assurance Manager sent FDA an email stating that the company issued a facility-wide recall "out of an abundance of caution and to support the practical administration of the recall." Defendants further stated, "We did not perform a risk assessment of products made elsewhere in the facility or make a specific determination that the products we supplied to [a buyer] were contaminated. For this reason, it would not be accurate for someone to believe based on the scope of the recall that we made a determination one way or the other that [the buyer's] products were contaminated." Defendants Edwin Rizo and Tomas Rizo were copied on the email.

35. On March 15, 2024 and April 12, 2024, Defendant Edwin Rizo, on behalf of Rizo Lopez, responded to FDA's List of Inspectional Observations, stating that, among other things, Rizo Lopez was

[1] Due to differences in the laboratory sequencing methods used by CDC and FDA, in February 2024 FDA analyzed data for twenty-five of the twenty-six clinical isolates collected by CDC. In May 2024, FDA analyzed the remaining clinical isolate and determined that all twenty-six clinical isolates match the identified strain of *L. mono*.

investigating potential contamination sources, revising policies and procedures, and implementing corrective actions.

36. On or about May 23, 2024, Defendant Edwin Rizo, on behalf of Rizo Lopez, provided a supplemental response to FDA's List of Inspectional Observations stating that, among other things, Rizo Lopez had implemented corrective actions and hired a new Quality Assurance manager. The supplemental response also stated that Rizo Lopez planned, "to restart cheesemaking operations for fresco cheeses as soon as June 3, 2024." The supplemental response did not include sufficient evidence to show that *L. mono* had been eradicated from the Facility.

37. On or about June 3, 2024, Rizo Lopez resumed food manufacturing operations, even though FDA still did not have sufficient assurance Rizo Lopez's food manufacturing operations were safe and that *L. mono* had been eradicated from the facility.

38. In an email dated June 13, 2024, Rizo Lopez informed FDA that it "has stopped manufacturing food" and that "[t]he last day of production was . . . June 12, 2024." Rizo Lopez currently receives, holds, and distributes pre-packaged food.

39. Defendants' responses and corrective actions are inadequate particularly given the ten-year history of a persistent strain of *L. mono* at Defendants' Facility that has resulted in multiple illnesses, including illnesses linked to two deaths and a fetal loss, as well as the recently observed insanitary conditions in Defendants' Facility. Adequate corrective actions would include, among other things, remediating the *L. mono* contamination, verifying through documentation that systematic contamination has been eradicated from the Facility, and establishing and ensuring adequate implementation of sanitation standard procedures for manufacturing food sufficient to identify and prevent contamination in the environment and products in the future. Without such corrective actions, there is a continued risk of *L. mono* contamination of the RTE foods manufactured at Defendants' Facility, posing a serious health risk to consumers.

40. The United States believes that, unless restrained by order of this Court, Defendants will continue to violate 21 U.S.C. §§ 331(a) and (k).

PRAYER FOR RELIEF

WHEREFORE, the United States respectfully requests this Court to:

I. Order that Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships), cease manufacturing, preparing, processing, packing, and/or distributing food at or from the Facility or at any other current or future location, unless and until Defendants bring their manufacturing, preparing, processing, packing and/or distributing operations for food into compliance with the Act and applicable regulations, to FDA's satisfaction;

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) from directly or indirectly from violating: (a) 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing to be introduced or delivered for introduction into interstate commerce, articles of food within the meaning of 21 U.S.C. § 321(f) that are adulterated within the meaning of 21 U.S.C. § 342(a)(4); and (b) 21 U.S.C. § 331(k), by causing articles of food within the meaning of 21 U.S.C. § 321(f) that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4);

III. Order that FDA be authorized to inspect Defendants' place of business and all records relating to the manufacturing, receiving, preparing, processing, packing, and/or distributing articles of food to ensure continuing compliance with the terms of the injunction, the costs of such inspection to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Order that Plaintiff be awarded costs incurred in pursuing this action, including the costs of investigation to date, and such other equitable relief as the Court deems just and proper.

Dated this 27th day of September, 2024.

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